

RESEARCH INSTRUMENTS LIMITED



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510(k) Summary 21CFR807.92(c)**Date prepared 21CFR807.92(a)(1)**

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Submitter's information 21CFR807.92(a)(1)

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Device Names 21CFR807.92(a)(2)

Device Name: Migration Sedimentation Chamber
Trade Name: Research Instruments Migration Sedimentation Chamber (RI MSC)
Common name: IVF Tissue Dish
Classification Name: Labware, Assisted Reproduction (21CFR 884.6160, 85 MQK)
Classification Panel: Obstetrics/Gynecology
510(k): K112413

Predicate Device 21CFR807.92(a)(3)

The RI MSC claims substantial equivalence to

Trade Name: IVF Center Well Dish
Common name: IVF Tissue Culture Dish
Manufacturer: Thermo Fisher Scientific
(Nalge Nunc International)
Classification Name: Labware, Assisted Reproduction (21CFR 884.6160, 85 MQK)
510(K): K090429

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**Description of the device 21CFR807.92(a)(4)**

The Research Instruments Migration Sedimentation Chamber (RI MSC) is sterile, non-pyrogenic proven by Limulus Amebocyte Lysate and non-toxic to sperm proven by Human Sperm Survival Assay (HSSA). The RI MSC is disposable and labelled for single use, individually packaged in medical pouches and sold in boxes of twenty (x20) units.

The RI MSC is manufactured from medical grade polystyrene and its surfaces are untreated. It is injection moulded as a completed unit, housing a central well with a surrounding gallery. The cylinder is 74 mm in height with a top OD of 16.5 mm and fluid capacity of 6 ml (approx) if completely filled; however, during recommended procedures it accommodates 1-2 ml of culture medium.

The RI MSC facilitates the migration sedimentation technique. The migration sedimentation technique utilizes the innate 'swimming' ability of sperm to separate vigorous, A-motile sperm from non-motile or abnormal sperm and ejaculate debris.

2 hours prior to the moment of insemination by assisted reproduction techniques (ART), the chamber is pre-loaded with culture media into which unprepared (raw) sperm is pipetted. The semen is pipetted into the gallery only section of the chamber. During a short incubation period, motile sperm migrate to the over-laying medium and fall by gravity from the gallery into the central well cavity of the chamber. The resulting sample is ready for use in ART techniques.

The RI MSC design is based on existing technology described in the published literature paper 'Selection of human spermatozoa by migration sedimentation' by Mailloux-G¹, Lucena-C, Tea-N-T, Jondet-M. *Contraception Fertilite Sexualite*, 1990, Vol.18 No.117 Pg 1037-1039.

Indication for Use 21CFR807.92(a)(5)

The RI MSC is intended to prepare sperm by migration-sedimentation method for the assisted reproduction techniques of intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI).

Although the intended use of the predicate device differs from that of the RI MSC, both devices interact with the sample or gamete in exactly the same way, i.e. the devices are receptacles which are filled with culture media into which a sample is placed.

The essential difference between the devices is that where the IVF Center Well Dish only 'holds' the sample (gamete or embryo), the RI MSC 'holds' the sample (gamete/sperm) and 'allows it to be prepared' by its own innate action, the interaction with the media contained within and the physical shape of the RI MSC which results in the collection of motile sperm in the central well.

These differences do not affect the safety and effectiveness of the device when used as labelled.



Technological Characteristics 21CFR807.92(a)(6)

Feature	RI MSC	IVF Center Well Dish
Indications for Use	Preparing sperm by migration-sedimentation method for the assisted reproduction techniques of intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI).	Preparing and culturing gametes or embryos for use in human In Vitro Fertilization (IVF).
Contraindication	Not recommended for sperm samples with total motility rate < 40%.	N/A
Target Population	Female ART patients	Female IVF patients
Design Features	Cylindrical container with internal gallery and well. Optically clear, with flat base.	Shallow circular container with 3 ml center reservoir, Optically clear, with flat base Supplied with lid.
Patient/embryo contact material	Polystyrene, non-treated	Polystyrene, non-treated
Sterility	Sterile (SAL 10^{-6}) gamma irradiated	Sterile (SAL 10^{-6}) gamma irradiated
Performance testing Bio-compatibility	- Tested non-pyrogenic by LAL - Human Sperm survival Assay (HSSA) $\geq 70\%$ motility at 24hr	Tested non-pyrogenic by LAL Mouse Embryo Assay (MEA) 1-cell at $\geq 80\%$ expanded blastocysts at 96 hours

The RI MSC and the predicate device IVF Center Well Dish, have similar applications which include the storage of gametes for Assisted Reproduction (AR) techniques. Both devices are sold sterile with SAL 10^{-6} and both are batch tested non-pyrogenic by LAL (Limulus Amebocyte Lysate). The containers are a single part, made of the same material polymer (Polystyrene) and are gamma irradiated.

The differences between the RI MSC and the IVF Center Well Dish (the predicate device) are

- the physical dimensions and shape of the containers i.e. the RI MSC is cylindrical with internal gallery and well. The IVF Center Well Dish is a shallow circular container with no internal configurations.
- the IVF Center Well Dish is supplied with a lid, the RI MSC is not.
- The IVF Center Well Dish is intended to hold gametes and embryos during fertilization via in vitro fertilization (IVF). The RI MSC is intended to hold and promote sperm migration and sedimentation in preparation for use in assisted reproduction techniques IVF, ICSI and IUI.
- The predicate device tests for compatibility with the sample by MEA (Mouse Embryo assay), whereas the RI MSC comes into contact with sperm only and is batch tested compatible by HSSA (Human Sperm Survival Assay).
- The RI MSC states a contraindication with regard to the type of sperm sample to be used while the predicate device does not state any contraindication. This is discussed in full in the Substantial Equivalency Discussion.

These differences do not affect the safety and effectiveness of the device.



Non-clinical Testing [21CFR807.92(b)(1)]

The RI MSC non-clinical testing includes

- sperm compatibility by HSSA to pass level: $\geq 70\%$ motility at 24 hours
- endotoxins by LAL to a pass level: $<0.5\text{Eu/device}$
- sterility assurance to a level of 10^{-6}
- shelf life of 3 years, proven by packaging validations and biocompatibility testing of accelerated aged samples.

Clinical Testing [21CFR807.92(b)(2)]

To our knowledge the RI MSC has not been involved in any clinical trials.

The migration sedimentation technique was developed by Tea¹ et al who used a glass tube with an inner cone to separate spermatozoa. The merits of this type of device and technique are discussed in a paper by Henkel² and of this type of device are discussed in a paper by Lesage³.

1. Tea-N-T, Jondet-M, Scholler-R (1984) A migration-gravity sedimentation method for collecting motile spermatozoa from human semen. In *In Vitro Fertilization, Embryo Transfer and Early Pregnancy*. Pgs 117-120
2. Henkel-R-R, Schill-W-B, (2003) Sperm preparation for Art. *Reproductive Biology and Endocrinology*. 1/1/108
3. Lesage-B, Vannin-A-S, Paramio-M-T, Emiliani-S, Debaisieux-L, Englert-Y, Leisnard-C (2006), Embryo development and structural analysis of invitro matured bovine oocytes vitrified in flexipet denuding pipettes. *Fertility and Sterility*, Vol 86, No 1, Pgs 121-128
4. Mailloux-G, Lucena-C, Tea-N-T, Jondet-M (1990), Selection of human spermatozoa by migration sedimentation. *Contraception Fertilite Sexualite*, Vol.18 No.117 Pg 1037-1039.
5. Yener-C, Mathur-S, Parent-B, (1990), Comparison of Two sperm preparation techniques using Automated Sperm Motion Analysis : Migration sedimentation versus Swim-Up *Archives of Andrology* Vol 25, Pgs 17-20
6. Maya-W-D-C, Gutierrez-J-A-B, de la Rios-J-R, Jaramillo-A-P-C-J (2007), Functional Evaluation of Sperm in Colombian Fertile Men. *Grupo Reproduccion* Vol 60, No 7, Pgs 827-831
7. Hauser-R, Homonnai-Z-T, Paz-G-F, Yavetz-H, Amit-A, Lessing-J-B, Peyser-M-R, Yagev-L (1992) Migration Sedimentation Technique as a predictive test for the fertilizing capacity of spermatozoa in an in vitro fertilization programme. *International Journal of Andrology*. Vol 15, No.6, Pgs 498-503
8. Schill-W-B, Kohn-F-M (1997) Therapy of Male subfertility. *Zentrum fur Dermatologie und Andrologie*. Vol147, No.4-5 Pgs 76-80 – see The Royal Society of Medicine literature search summaries no. 3

Conclusions [21CFR807.92 (b)(3)]

The RI MSC is substantially equivalent to the predicate device and performs as intended and described in the published medical literature.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. David Lansdowne
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JUL 13 2012

Re: K112413
Trade/Device Name: Research Instruments Migration Sedimentation Chamber (RI MSC)
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: June 25, 2012
Received: June 28, 2012

Dear Mr. Lansdowne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

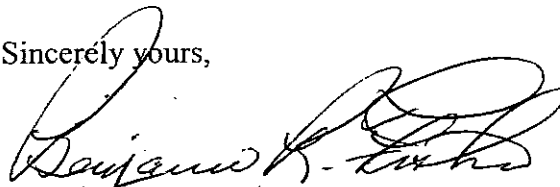
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over the typed name.

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K112413

Device Name: Research Instruments Migration Sedimentation Chamber (RI MSC)

Indications for Use:

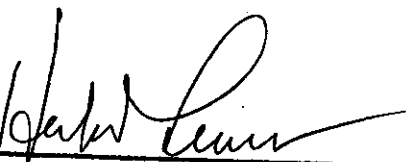
The RI MSC is intended to prepare sperm by migration-sedimentation method for the assisted reproduction techniques of intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI).

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use No
(Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K112413

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